Review Article

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Informed consent: Past and present

INTRODUCTION

Informed consent is one of the key elements for protection of welfare of patients or research participants. Traditionally, irrespective of various cultural environments, whether in ancient India or during the Greco-Roman period, physicians were paternalistic in attitude and consent from patients was more of defensive medicine practice. However, the socio-cultural differences of those times persist even in modern times regarding obtaining informed consent despite existing guidelines/regulations for reducing exploitation. The vulnerability of patients/participants with reduced autonomy is universal, but application of an ethical principle of respect for persons depends on the political environment and cultural differences across the world.

Indian traditional systems of medicine

In the Indian traditional systems of medicine, namely, *Ayurveda*, *Siddha*, and *Unani*, as fiduciary responsibility, a physician was expected to see that the patient did not come to any harm due to treatment. Within this boundary these systems had experiential basis in evolving treatment modalities in the best interest of the patient, but if this was presumed to result in considerable harm or even death, permission of the relatives, community, and even the State Head (Kings) used to be sought but not that of the patients themselves. This was expressed more or less in the same manner in all the classical texts of the traditional systems of medicine. For example, *Sushrutha Samhita*,[1] a treatise on surgery, mentions that permission from the king should be sought when a situation warrants that "if surgical intervention is not done then the patient will die and after surgery it is not certain if surgery will be beneficial". The same type of expression is stated in *Caraka Samhita*,[2] a classical text of medicine. *Arthasastra*, another text of 3rd century B.C, even mentions capital punishment to physicians who have not taken prior permission before performing major surgery, which could result in death.[3] This reflects a sort of defensive medicine where the physician is expected to safeguard himself from harm in adverse outcomes. Theraiyar (one of the Siddhars) in his treatise *Thylavarga Churukkam* enlists the qualities required for a person to become a physician, which includes compassion. *Agathiyar sillaraikkovai* says that the physician should protect his patients like an eyelid, but patients' preferences are not mentioned in decision-making, indicating that the Siddha systems too reflected paternalism. According to the 10th century A.D. book "*Kamilussanah*", authored by Ali ibn Abbas al-Majoosi, the Unani physicians were to follow a code of conduct,[4] which again appears to be paternalistic in nature.

Ancient Greece

In ancient Greece, the society was constituted of freeborn men and slaves. So a doctor could have apprentices/trainees who belonged to either group. Although after training they too acquired the art of medicine to be called as "doctors"; Plato described trainers as real doctors and apprentices/assistants as others. These so-called doctors treated patients differentially according to their societal status.[5] When slave doctors treated slaves they never explained the details of treatment to them. But freeborn doctors, who mainly treated freeborn patients, described to them the nature of their illness, often not revealing the whole truth regarding the condition or its prognosis, and prescribed medicine to them only after obtaining their consent. Sometimes a person trained in speaking to the public or doctors trained to persuade a

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person were called in to obtain consent. Plato describes in his book "*The Statesman*" that if a doctor forces his patient to do the right thing against the accepted norms, it would not be considered as an error. Hippocrates before Plato stated that information needed to be given to the patient to enable her/him to cooperate with the physician to give consent. Although this is not reflected in the older version of Hippocrates Oath, glimpses of defensive medicine are evident in his writings elsewhere. An extreme example is related to Alexander, the Great. During his march in Asia, he suffered from an almost fatal disease. On account of the severity of the disease and his own strict nature, no physician dared to treat him. Finally an eminent military physician, Philip of Acarnania, treated him under strong pressure from the Emperor only after he declared in public his trust in the physician. On another occasion, when he was seriously wounded, Critobulus, an eminent physician, operated on him only after he (Alexander) declared prior to operation that his condition was incurable. There is also mention of powerful patients such as kings offering sword to the physician before operation, symbolizing that they not only gave informed consent, but also "informed request" to be operated. This way it would appear that "if God willed healing then the physician would boast and if not, the latter will not be blamed."

Modern times

In modern times too, especially in the 20th century, despite there being guidelines/regulations to prevent exploitation by ensuring that informed consent has been taken, absence of that procedure or persuasion in various forms to obtain it exists even today.

Early philosophers spoke about "natural rights" that confer meaning of life from the time one is born, but in modern day parlance these are termed "fundamental human rights," which are applicable in democratic countries and endorsed in international instruments. Socrates, Plato, and Aristotle recognized the purpose of ethics and analyzed normative ethical ideals affecting human life. However, later by the early part of 20th century, the concentration of philosophers got diverted to linguistic details or "logical analysis" of "moral semantics and other issues in meta-ethics." Interestingly, when the German government's guidelines in 1931, emphasizing on present day requirements of informed consent and independent ethics review, were flouted by physicians influenced by the political ideology prevailing then, the shocking Nazi human experiments shook the philosophers awake. This gave rise to the much-acclaimed code–the Nuremberg Code. Among its 10 principles the longest principle is on informed consent. Later, the Helsinki Declaration stated the importance of having an ethics committee review a research proposal, which included an informed consent document comprising patient/participant information sheet and informed consent form. This was expected to put the nail on the coffin of paternalism, but in hierarchical social systems, mostly in developing countries, this is still a reality.

The earliest documented evidence of informed consent form was a contract, which Major Walter Reed asked his volunteers in Spain to sign for his experiment on causation of Yellow fever infection.[6] Interestingly it had a translated Spanish version also, a concept insisted upon in the present times in India due to different local languages even in the same geographical area. Surgical records from Massachusetts General Hospital from 1840s to 1860s, New York Hospital from 1840s to 1850s, and fracture books of Pennsylvania Hospital from 1850s to 1860s throw some light on instances when patients objected to surgical procedures. But at the same time, benevolent decisions on behalf of the patient without involving her/him were also made. In 1914 in US, for the first time the case law on *Schloendorff v. Society of New York Hospitals* gave the term "informed consent" a legal standing when the court gave a decision in favor of a competent Mrs. Schioendorff who had consented to abdominal examination under anesthesia but was not informed about the tumor, which was removed by the surgeon without informing her about the possible adverse outcome.[7] Much later the infamous Tuskegee Syphilis Study of the Public Health Services Department of the US government from 1932 to 1972, when the Nuremberg Code was in place since1947, led to the issue of Belmont Report by US in 1979. The report highlighted three main ethical principles while conducting research, namely, respect for persons, beneficence, and justice.[8] Respect for persons relates to autonomous decisions by a "prudent" (reasonable or average) patient to volunteer to enroll in research after comprehending the involved risks and benefits. The pre-requisites of informed consent are that the patient or research participant should be competent and the disclosed facts should be comprehended before giving consent freely. Courts rely on "prudent patient test" to see if adequate information was given to the patient/participant. However, cultural differences can influence decision regarding full disclosure. For instance, the Navajo tribe in US does not want to know negative information as it believes this could lead to harmful effects. They feel that thought and language could be powerful to shape events in positive way.

In developing countries where hierarchy in community still exists, application of autonomy to give consent out of free will does not apply in spite of constitutional freedom. In such circumstances, harmony of the environment is

more important and safeguards should be in place not to disturb this while obtaining informed consent. Also, often participants consent more out of fear of consequences of withdrawal, which could include decreased access to healthcare.[9] While US recognizes five competing claims regarding informed consent, namely, public health emergencies, medical emergencies, incompetence to judge, therapeutic privilege, and waiver from making decision as an informed choice of the individual (Hana Osman), these could create controversial positions in legal battles. The situation would be even more complex in developing countries. However, in India, despite legal right to autonomy and self-determination as per Article 21 of the constitution, a physician need not get consent for treatment in medical emergencies under Section 88 of the Indian Penal Code.[10]

Soon after the release of the Belmont Report, in 1980, the Indian Council of Medical Research (ICMR) also released its first ethical guidelines as "Policy Statement on Ethical Considerations Involved in Research on Human Participants".[11] Under the topic of informed consent it states "the best way of obtaining informed consent is one that is difficult and one in which the norms and forms used in other countries are really not fully relevant to the conditions prevailing in this country." Further it states that the council can only lay down broad guiding principles to obtain informed consent and leave it to the ethics committees to develop its own procedures to review that. This ethical relativism was recognized even at that time. However, in the first revised versions of ICMR's ethical guidelines released in 2000[12] individual's consent was considered as important as permission from community gatekeepers. In the second version in 2006[13] more emphasis was given to community participation and permission from culturally appropriate authority on account of increasing number of community-based studies in India.

Informed consent–specific points

Consent is implied or implicit when a physician is allowed to do routine physical examination and investigations. This gets more restricted when a female patient has to be examined in a more intimate manner and when invasive investigations are required. The consent here will have to be more explicit in oral or written form. But when more risky interventions, surgical procedures, and long-term follow-up are involved, written consent is required as a safeguard. Any violation by a physician or researcher can be liable under tort or criminal law, and the patient can sue for battery or negligence depending on the extent of alleged offence.

In the case of minors and incompetent participants, parents or legally authorized representatives can give consent. Consent from minors is termed assent. In India consent from minors is from the age of 7 to 18 years. Competency of a minor to give a decision would be applied as per Indian Majority Act.[14] Any coercion, undue influence, mistake, or fraud would nullify the contractual consent. Mechanisms are available to take informed consent from adolescents in sensitive projects where confidentiality is a crucial issue to get to the problem. In UK, General Medical Council guidelines confer consenting age to 16 years old. Generally a child's refusal is respected but has been overridden by court in child's best interest in some instances except in Scotland. In US, "emancipated minors" are adolescents below the age of 18 who can give consent if they are married, widowed, or divorced; or have a child or are pregnant; are in the armed forces; or have the earning capacity to manage to live separate from their parents. In some states, minors above 16 years who have mental illness, and those above 12 years who are being treated for drug addiction or other illnesses dangerous to public health such as venereal diseases, etc., can give consent.[15]

Informed consent violations

There are several instances internationally and nationally where informed consent has not been taken for treatment or research. Every such event has led to political reaction mostly as a knee jerk phenomenon. Sometimes careful planning has given shape to concrete policies. The Tuskegee trial in US is an example, which 7 years later led to the Belmont Report for human protection. Mainly drug companies in the developing world have perpetrated many violations in the form of absence of informed consent or deception by withholding vital information on risk. Scandals related to drug development have not spared the academia too as seen in the involvement of Johns Hopkins University for a drug trial in the Regional Cancer Centre in Trivandrum, India. Non-provision of informed consent form in the local language of one of the participants was one of the issues concerning this trial. There are many other unethical trials in India where the participant was ignorant about her/his enrolment or of the details of the trial, which could cause bodily harm.

Very recently, major issues pertaining to informed consent involved Human papillomavirus (HPV) vaccine trial and unethical trials conducted in Bhopal and Indore. Activist groups and the media highlighted these, leading to reactions from the Government of India. In the HPV trial it is clear that the concept of informed consent in the case of institutionalized minor tribal girls (vulnerable by age and lower socio-economic status) was either not understood or not taken seriously by both the NGO, PATH, and the government officials in the state of Andhra Pradesh. The local language in the pamphlets

regarding the vaccine, which were circulated, was so literary in nature that the local population could not comprehend it. There appeared to be misconception on the part of the public that this was part of government's immunization program. In the Bhopal and Indore clinical trials there was deception or absence of informed consent from the enrolled vulnerable population.

Solutions

It is evident that India needs a robust system of monitoring of research by both ethics committees and regulatory agencies. The sponsors, Contract Research Organisation (CROs), and the institutions should also be held liable for violations concerning informed consent as per ICMR's general ethical "Principle of Totality of Responsibility." Although the ethical guidelines are not yet legislated, they are indirectly mandated through amendment of Indian Medical Council Act, 2002, and Schedule Y of Drugs and Cosmetics Act, 2005. Shortly the bill based on ICMR's ethical guidelines will be finalized for legislation. Nevertheless, the existing legal system is good enough to initiate punitive measures if the judicial and political forces are applied fairly. Unfortunately in the Indore incidence, the punishment meted out to the practitioners who had grown very rich as a consequence of unethical drug trials was very meager for the offence committed. Political will is an important factor in controlling unethical practices. Therefore, consultations with policymakers, initiation of awareness programs among the public regarding clinical trials to empower it to make informed choice, and training to ethics committee members and investigators on ethical guidelines and relevant legal positions would improve the situation regarding protection of rights of patients/participants with respect to treatment and or research.

All stakeholders in clinical research have a role to set right the ethical and regulatory environment. Government agencies such as ICMR have pioneered education with regard to ethics by running short-term and long-term (including Diploma) programs[16] mostly through external funding from WHO and National Institutes of Health, USA. National AIDS Control Organization and Department of Biotechnology are also making moves in this direction. Other international funding agencies have also collaborated for holding regional workshops. India now has a core group of internationally trained Fogarty and Erasmus Mundus trainees in bioethics besides and national trainees to strengthen support in this direction by holding workshops, preparing curriculum, and presenting Indian positions in the Global Fora. Drug companies have also come forward to support awareness programs. The Indian Society for Clinical Research has also organized regional workshops to sensitize ethics committee members and investigators.

The Forum for Ethics Review Committees in India (FERCI), the national chapter of Forum for Ethics Review Committees of Asia Pacific region, has contributed to capacity-building by holding workshops for ethics committee members to discuss specific issues and formulating guidelines in specific areas.[17] In collaboration with Pfizer, it has created an educative DVD on informed consent and a speaking book, which is in English, Hindi, and Telugu, to educate potential participants regarding what clinical trial is all about. Quality of ethics committee review can add to research participant protection. Therefore, FERCI held a training program for the non-scientist members of ethics committees to empower them to represent a participant's view in the best possible manner. Recognition of ethics committees on a voluntary basis by two global agencies, namely SIDCER (Strategic Initiative for Developing Capacity for Ethical Review) and AAHRPP (Association for the Accreditation of Human Research Protection Programs), has been initiated in India in a very small way. More and more institutions need to take interest in getting their ethics committees accredited to safeguard the interest of the participant by doing quality review of the research proposal, informed consent document, and randomly monitoring the conduct of research.

CONCLUSION

From ancient times, physicians' paternalistic attitude toward a patient has shifted to informed consent from early 20th century onwards. It became more stringent in some geographical areas. Culturally, in the developing countries where community living is strong, an individual's right about making informed choice has to be combined with community support. Instances of violations of informed consent have occurred world over despite existence of ethical principles and regulatory mechanism. In order to improve the situation, awareness programs and more aggressive training for various stakeholders are required through international and national efforts.

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